



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OPPTS/OPP/RD/TRB/PRODUCT CHEMISTRY TEAM

WASHINGTON, D.C. 20460

DATE: 25/JUL/2001

**SUBJECT:** PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]  
DP BARCODE No.: D275563  
REG./File Symbol: 9404-IT  
PRODUCT NAME: Permethrin 0.25% Insecticide Granules  
COMPANY: Sunniland Corp.

**FROM:** Linda L. Kutney, Chemist  
Product Chemistry Team  
Technical Review Branch/RD (7505C)

*Linda L Kutney*  
*7/25/01*

**TO:** Arnold Layne, Linda Gerber PM 3  
Insecticide Branch/RD(7505C)

INTRODUCTION

The Sunniland Corp. has sent (in a letter dated 6/4/01) a me-too registration request for their insecticide, Permethrin 0.25% Insecticide Granules, based on its reported similarity to Micro Flo Company's (now Aventis Corporation's) Permethrin 0.25% Granules, Reg. No. 51036-322.

The proposed CSF for Sunniland's Permethrin 0.25% Insecticide Granules contains [REDACTED] pure permethrin a.i. which is a source of the nominal 0.25% permethrin in the proposed end-use product. Product chemistry data supplied in support of this request have been assigned MRID number 452546-01. The intended use of Permethrin 0.25% Insecticide Granules is a non-food use on residential lawns, ornamentals, recreational turf and golf courses.

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## FINDINGS

- The Agency was informed, in a 6/4/01 FAX of a letter from consultants H. R. McLane, Inc., that [REDACTED] has agreed to support this registration request for Permethrin 0.25% Insecticide Granules, partly because [REDACTED] is the a.i. source.
- The densities, pH's, and flash points/flame extensions of Permethrin 0.25% Insecticide Granules are essentially identical to Permethrin 0.25% Granules, Reg. No. 51036-322."
- The Physical or Chemical Hazard statements on the proposed label for Permethrin 0.25% Insecticide Granules are appropriate with respect to its flammability and satisfy the requirements specified in 40 CFR 156.10 (h)(2)(iii).
- The analytical method requirement (40 CFR 158.180) has been previously satisfied.

## CONCLUSIONS:

TRB has reviewed this submission and concluded that Sunniland Corporation's Permethrin 0.25% Insecticide Granules can not be declared substantially similar to Avenis's Product, Permethrin 0.25% Granules, Reg. No. 51036-322, until the deficiencies *italicized* below are adequately addressed and submitted to the Agency for additional consideration.:

- *The proposed storage and disposal instructions must be revised to correctly spell out, "Store product in original container in a locked cool, dry storage area out of reach of children and pets " in accordance with PR 83-3.*
- The nominal concentration of the permethrin product a.i. agrees with the label concentration, in accordance with the requirements of PR 91-2. *The proposed 6/4/01 CSF identifies the a.i. as [REDACTED] in column 10. The chemical name of the a.i., permethrin, must be as is listed on the label in the CSF, column 10, along with the purity of the permethrin.*
- *Column 11 of the proposed 5/18/01 CSF should give the full supplier name and address for all components in the label.*
- *Guideline submissions for 830.1550 (Product Identity) and 830.1750 (Certified limits) do not satisfy 40CFR§158.155 and 158.175, respectively, because the study states the [REDACTED] the CSF states the ai is [REDACTED] Sunniland must provide a clear, consistent description of product identity and certified limits within their study and proposed CSF.*

- *Guideline 830.1600 (Beginning Materials) and Guideline 830.1620 (Formulation Process) must be provided. Data given in the study must be consistent with the proposed CSF.*
- *Guideline requirements withing 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics) are expected to satisfy the requirements for the Permethrin 0.25% Insecticide Granules, when similarity between the Summiland product and the Aventis product is established.*

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PRODUCT NAME: Permethrin 0.25% Insecticide Granules  
COMPANY: Sunniland Corp.

1. Reviewer: Linda L. Kutney
2. Company: Sunniland Corp.
3. Type of Submission: Registration ☒ Reregistration ☐ New ☒ Resubmission ☐  
Amendment ☐ "ME-TOO" ☒ Alternate Formulation ☐ Experimental Use  
Permit ☐ Other (Specify)
4. If "Me-TOO" Registration, this product is ☒ is not ☐ similar or substantially similar  
to EPA's Reg. No.:  
If not, comment in Confidential Appendix A on the differences between the registered and  
new source, where applicable

#### CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
  - Non-integrated formulation system.....☒
  - Are all technical grade active ingredients used registered? ● yes ☒ ● no ☐, If no,  
specify The technical is under process of registration
  - Integrated formulation system.....☐
6. Clearance of intentionally added ingredients in the formulation for the intended use  
(indicate in the Confidential Appendix those that are not cleared; the PC Codes should be  
provided by the chemist on the CSF for those that are cleared):
  - 6(a) Formulation intended for food use under 40CFR§180.1001:
    - yes ☐ ● no ☒ ● Some are cleared, others are not ☐
    - Cleared under list: ● c ☐ ● d ☐ ● e ☐ Are there any limitations for use as an  
inert under 40CFR§180. 1001?
      - yes ☐ ● no ☐, If yes, specify
  - 6(b) Formulation intended for non-food use:
    - yes ☒ ● no ☐ ● Some are cleared, others are not ☐

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).

• yes ☐ • no ☐ • Some are cleared, others are not ☐

If yes, the entire formulation is cleared under 21CFR§

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 830.7300(density), 830.7000(pH), and 830.6315(Flammability), respectively:

• yes ☒ • no ☐

8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
Permethrin, [REDACTED]	0.25	0.28	0.225

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:

• yes ☒ • no ☐

10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:

• yes ☒ • no ☐

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes ☐ • no ☒

*The proposed 6/4/01 CSF says only [REDACTED] in column 10 for the ai, it must also give the chemical name, permethrin, along with its purity.*

12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:

• yes ☐ • no ☐ • not applicable ☒

13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:

• yes ☒ • no ☐

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**PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED**

**PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)**

14. Chemical IDs/Manufacture/ Analytical Information New Guideline:830.--	Data Required Fulfilled	MRID No.
1550. Chemical Identity(CSF)	<i>No</i> <i>Study states</i> [REDACTED] <i>CSF states</i> <i>ai is</i> [REDACTED]	452546-01 6/4/01 CSF
1600. Beginning Materials  1620. Formulation Process	<i>Not provided,</i> <i>study lists</i> <i>different inerts</i> <i>than 6/4/01</i> <i>CSF</i>	452546-01 6/4/01 CSF
1750. Certified Limits (CSF)	<i>No</i> <i>Study states</i> [REDACTED] <i>CSF states</i> <i>ai is</i> [REDACTED] <i>&amp; contains</i> <i>different inerts</i> <i>than 6/4/01</i> <i>CSF</i>	452546-01 6/4/01 CSF
1800. Enforcement of Analytical Method (required for integrated products & those of tox. concern)	Yes, already available for permethrin	
1900. Submittal of Samples (required for integrated products, those of tox. concern, and for nonintegrated products with interference, etc, method problems)	N/A	

15. <u>Physical/Chemical</u> <u>Properties</u> New Guideline No. 830.---	<u>Data</u> <u>Required</u> <u>Fulfilled</u>	<u>Value or</u> <u>Qualitat.</u> <u>Descrip.</u>	<u>MRID No.</u>
6302. Color (if required by PR 92-5)	Yes	tan	452546-01
6303. Physical State	Yes	granules	452546-01
6304. Odor (if required by PR 92-5)	Yes	earthy	452546-01

6314. Oxidation Reduction Reaction	N/A		452546-01
6315. Flammability/Flame Extension	N/A	> 500 F	452546-01
6316. Explodability	Yes	Contains no explosive ingredienets	452546-01
6317. Storage Stability	Yes	Reported as stable product, acceptable due to me-too product stability	452546-01
6319. Miscibility	N/A	granule	452546-01
6320. Corrosion Characteristics	Yes	Reported as stable product, acceptable due to me-too product stability	452546-01
6321. Dielectric Breakdown Voltage	N/A	granule	452546-01
7000. pH	N/A	granule	452546-01
7100. Viscosity	N/A	granule	452546-01
7300. Density/Bulk Den.	Yes	29-32 lb/ft3	452546-01

NA = Not Applicable;